SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 6361-6380

Adulteration, Section 501(a)(1), the article consisted in part of a filthy substance; and Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(i)(2), the article was an imitation of another drug; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling; Section 502(1), the article was composed wholly or in part of penicillin, or chloramphenicol, and was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; and Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

## DRUG AND DEVICE ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

## DEVICE FOR HUMAN USE

6361. Thiede's head harness. (F.D.C. No. 44757. S. No. 18-041 R.)

QUANTITY: 2 devices at Billings, Mont.

SHIPPED: About March 1959, from Idaho Falls, Idaho, by Thiede Enterprise, Inc.

LABEL IN PART: "Thiede's Stretch to Health Head Harness Company, Idaho Falls, Idaho."

ACCOMPANYING LABELING: Pamphlet entitled "A Simple Improved Method for Vertebral Traction."

RESULTS OF INVESTIGATION: The article consisted of a head harness and accessories intended for supporting the head while the rest of the body would dangle, thus pulling on the neck muscles.

LIBELED: 7-27-60, Dist. Mont.

CHARGE: 502(j)—when shipped, the article was dangerous to health when used as directed in its labeling.

Disposition: 8-23-60. Default—destruction.

## DRUG FOR VETERINARY USE

6362. Black Widow Smear (veterinary). (F.D.C. No. 44705. S. No. 19-184 R.)
QUANTITY: 6 16-oz. jars, 10 32-oz. jars, and 4 1-gal. jars at Artesia, N. Mex.